

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715		DATE(S) OF INSPECTION 11/11/2024-11/19/2024*	
		FEI NUMBER 3005180920	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Francesco Siccardi, CEO			
FIRM NAME Medacta International, SA		STREET ADDRESS Strada Regina, Castel San Pietro	
CITY, STATE, ZIP CODE, COUNTRY Ticino, 6874 Switzerland		TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
<i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established. Specifically, your Complaints Handling Procedure (PO 08.05/ Rev. 18) does not include the requirement for immediate documentation of the complaint information upon receipt. Additionally, under the Risk Assessment table "RF" (risk factors) 2 (The event led to death or serious injury) and 3 (The event might have led to death or serious injury) should be considered equally when evaluating for adverse event reporting.			
*DATES OF INSPECTION 11/11/2024(Mon), 11/12/2024(Tue), 11/13/2024(Wed), 11/14/2024(Thu), 11/15/2024(Fri), 11/18/2024(Mon), 11/19/2024(Tue)			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Wendy M Stone, Investigator		DATE ISSUED 11/19/2024
		Wendy M Stone Investigator Signed By: 2001899733 Date Signed: 11-19-2024 07:18:02 X	

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Annotations to Observations Observation 1: Corrected and verified			
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 of 2 PAGES			

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."